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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WALLENHORST, MAUREEN

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 12/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/986,613	SATO, TOMOYA	
	<b>Examiner</b>	<b>Art Unit</b>	
	Maureen M. Wallenhorst	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☐ Responsive to communication(s) filed on \_\_\_\_.

2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) 1-16 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_ is/are allowed.

6) ☒ Claim(s) 1-16 is/are rejected.

7) ☐ Claim(s) \_\_\_\_ is/are objected to.

8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) ☒ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some \* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____
2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u> .	6) <input type="checkbox"/> Other: _____

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1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.
2. The disclosure is objected to because of the following informalities: On pages 6-9 of the specification, the brief description for figures 2, 3, 4, 5, 6, 7, 9, 10, 11, 12, 13, 14, 16, 17, 18, 19, 25, 26 and 27 should be changed to include the different embodiments of each figure, i.e. --Figs. 2A and 2B—rather than “Fig. 2”, --Figs. 9A, 9B and 9C—rather than “Fig. 9”, etc.

Appropriate correction is required.

3. Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

On lines 1 and 4 of claim 1, the phrase “and/or” is indefinite since it implies two different, non-equivalent conditions. See this same problem in claims 2-8. On line 2 of claim 1, the phrase “the absorption or emission spectrum” lacks antecedent basis. See this same problem on lines 3-4 of claim 8. Claim 1 is indefinite since it is not clear whether the appearance of the spectra at the at least two wave numbers serves as a positive indication that the specimen of cells tested is diseased. The last step of the method should be rewritten to positively recite this as the last step of the method. See this same problem in claim 8.

On lines 1-2 of claim 9, the phrase “the absorption of emission spectrum” lacks antecedent basis. See this same problem on lines 2-3 of claim 16. Claim 9 is indefinite since it is not clear what the appearance of the spectra at the at least two wave numbers serves to indicate about the drug. See this same problem in claim 16.

still a problem

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4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Cohenford et al (WO 97/18566, submitted in the Information Disclosure Statement filed on Jan. 4, 2002).

Cohenford et al teach of a method to identify cellular abnormalities in cells, which are associated with disease states such as premalignant and malignant stages of cervical cancer. In the method, the infrared absorption spectrum of a dried sample of cells on a transparent matrix is obtained in the specific region from 3000-950  $\text{cm}^{-1}$ . The identification of a sample as in a disease state, i.e. cancerous, is based upon a comparison of the spectrum obtained with the test sample to representative spectra of normal, dysplastic and malignant specimens. Variations in the absorption spectrum of the test sample at at least one range of frequencies in the range measured (3000-950  $\text{cm}^{-1}$ ) are detected, and the presence of the variations is indicative of a premalignant or malignant condition. Variations at two or more wave numbers within the range of frequencies measured are detected, i.e. variations in the regions of 1250-1000  $\text{cm}^{-1}$ , 1420-1330  $\text{cm}^{-1}$  and 3000-2800  $\text{cm}^{-1}$ . See page 15, lines 5-9 and page 18, lines 7-11 of Cohenford et al. Therefore, Cohenford et al teach of a method for determining a disease (i.e. cancer) in a sample of cells by analyzing the absorption or emission spectrum of the sample in a specific region (i.e. 3000-950  $\text{cm}^{-1}$ ), and determining the disease type or state by using as indices the appearance of spectra (i.e. variations) corresponding to at least two wave numbers (1250-1000  $\text{cm}^{-1}$ , 1420-1330  $\text{cm}^{-1}$  and 3000-2800  $\text{cm}^{-1}$ ) within the specific region.

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6. Claims 1-3 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Oong et al.

Oong et al teach of a method for detecting abnormalities in cells using infrared spectroscopy. A beam of infrared light is directed at a test specimen of cells so as to measure an absorption or emission spectrum in a certain region. An abnormality of the cells such as cancer is detected by spectral analysis of the infrared absorption spectrum of the sample at at least one range of frequencies to ascertain whether at least one change in the infrared absorption characteristics has occurred, which is characteristic of the abnormality. The change in the infrared absorption characteristic can be a change in absorption intensity at a particular frequency. For example, Oong et al teach that changes in absorption intensity between normal cell samples and malignant cell samples occur at frequencies/wave numbers of 1025, 1047, 1082, 1155, 1244 and 1303  $\text{cm}^{-1}$ . See Figure 2 and lines 42-57 in column 4 of Oong et al. Therefore, Oong et al teach of using the appearance of spectra corresponding to at least two wave numbers within the region measured as indices of disease (i.e. malignancy) for a tested specimen of cells.

7. Claims 1-3 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Wong et al.

Wong et al teach of a method for detecting anomalies in biological cells using infrared spectroscopy. A beam of infrared light is directed at a sample of cells, and the anomaly is detected at at least one range of frequencies by determining whether changes in infrared absorption have occurred due to the vibration of at least one functional group of molecules present in the sample, which is characteristic of the anomaly. Wong et al teach that the infrared spectra from control and cancerous cell samples in the frequency ranges of 1300-1800  $\text{cm}^{-1}$  and 2800-3050  $\text{cm}^{-1}$  are compared to the same ranges of absorption in the test sample. Wong et al teach that spectral changes occur between healthy and cancerous cells at frequencies or wave

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numbers of around 1082, 1170, 1230, 1380, 1713, 2850 and 2960  $\text{cm}^{-1}$ . See lines 23-30 in column 4 of Wong et al. Therefore, Wong et al teach of using the appearance of spectra corresponding to at least two wave numbers within the region measured as indices of disease (i.e. cancer) for a tested specimen of cells.

8. Claims 1-3 and 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Zakim et al.

Zakim et al teach of a method for the diagnosis of disease by infrared analysis of cells. The method comprises the steps of measuring a first spectra in a predetermined frequency range for cells that are free of dysplasia, measuring a second spectra in the same predetermined frequency range for a test sample of cells, comparing the first and second spectra for variations in frequency bands for indicating dysplasia and diagnosing a level of dysplasia based on the number and magnitude of variations between the first and second spectra. The predetermined frequency range in which measurements are made is between 600-4000  $\text{cm}^{-1}$ . According to Fig. 9 in Zakim et al, differences in the spectra between normal cells and dysplastic cells occur at the frequencies or wave numbers of 1025, 1040 and 1050-1054  $\text{cm}^{-1}$ . See lines 14-18 in column 16 of Zakim et al. According to Fig 11, lines 24-43 of column 17 and lines 1-11 of column 18, differences in the spectra between normal cells, dysplastic cells and cells infected with HPV virus occur at 970, 1000 and 1100  $\text{cm}^{-1}$ . Therefore, Zakim et al teach of using the appearance of spectra corresponding to at least two wave numbers within the region measured as indices of disease or virus infection for a tested specimen of cells.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 1-12 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 285296 (submitted in the Information Disclosure Statement filed Jan. 4, 2002) in view of any one of Cohenford et al, Oong et al or Wong et al. For a teaching of Cohenford et al, Oong et al and Wong et al, see previous paragraphs in this Office action.

JP 285296 ('296) teaches of a method and apparatus for judging a transformed state of bioactivity in substances such as cells by performing spectral analysis in a specific region of bioactivity of the cells to obtain a characteristic spectrum indicating a characteristic of the transformed bioactivity. A transformed state of the cells is determined depending upon an appearance state of the spectrum. The apparatus comprises an irradiating section 4 for irradiating cells with quantum energy, a detecting section 6 for detecting a spectrum of bioactivity, and an operational processing section 8, which analyzes the spectrum to obtain the detected spectrum in a specific range of frequencies as a characteristic spectrum indicating a characteristic of the transformed bioactivity. The spectrum of the cells is compared to the spectrum which is characteristic of a transformed state of bioactivity in order to diagnose the

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transformed state in the cells themselves. Spectral analysis is performed on both normal and cancerous cells. Characteristic spectra are always observed in malignant cells, but not in normal cells. JP '296 teaches that one example of a characteristic spectrum in the infrared range for a malignant cell is  $1261.4\text{ cm}^{-1}$ . Therefore, at this wave number, the spectra differ between normal and cancerous cells. With the characteristic spectrum of malignant cells, it is possible to judge whether or not normal cells have been transformed into malignant cells by comparing the spectra of the normal cells to the spectra of the malignant cells at certain defined wave numbers, i.e.  $1261.4\text{ cm}^{-1}$ . JP '296 teaches that either the measurement of an absorption or an emission spectrum can be measured and compared between a normal and a cancerous cell sample. JP '296 teaches that it is possible to judge the transformed states of cells, bacteria, viruses, anti-cancer agents, etc. JP'296 fails to teach that the comparison of spectra between normal and malignant cells can be performed at more than one frequency or wave number.

However, based upon a combination of JP '296 and either Cohenford et al, Oong et al or Wong et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to compare the spectra taught by JP '296 between normal and malignant cells at more than one frequency or wave number (i.e. other than  $1261.4\text{ cm}^{-1}$ ) since any one of Cohenford et al, Oong et al and Wong et al disclose that the infrared absorption spectra between normal cells and diseased cells differs from one another at multiple frequencies or wave numbers, thus giving multiple indications that a test sample of cells is either malignant or normal.

12. Claims 9-11 and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 286740 (submitted in the Information Disclosure Statement filed Jan. 4, 2002) in view of any



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one of Cohenford et al. Oong et al or Wong et al. For a teaching of Cohenford et al, Oong et al and Wong et al, see previous paragraphs in this Office action.

JP 286740 ('740) teaches of essentially the same method and apparatus for judging a transformed state of bioactivity in substances such as cells as does JP '296 described in previous paragraphs. However, JP '740 additionally teaches that the method can be applied to the development of anti-cancer agents, antibiotics and anti-virus agents. JP '740 also fails to teach that the comparison of spectra between normal and malignant cells/agents can be performed at more than one frequency or wave number.

However, based upon a combination of JP '740 and either Cohenford et al, Oong et al or Wong et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to compare the spectra taught by JP '740 between normal and malignant cells/agents at more than one frequency or wave number since any one of Cohenford et al, Oong et al and Wong et al disclose that the infrared absorption spectra between normal cells and diseased cells differs from one another at multiple frequencies or wave numbers, thus giving multiple indications that a test sample of cells is either malignant or normal.

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Nordstrom et al, Wong, Helfer et al, Cohenford et al (US Patent nos. 6,031,232, 5,976,885 and 6,146,897), Dukor et al and Haaland et al who teach of the measurement of the infrared spectrum of cells for the classification of the cells as either normal or diseased.

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14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 703-308-3912. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Maureen M. Wallenhorst  
Primary Examiner  
Art Unit 1743

mmw

November 25, 2002

*Maureen M. Wallenhorst*  
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